UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

PFIZER INC., PFIZER LIMITED and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs and Counterclaim Defendants, v. TEVA PHARMACEUTICALS USA, INC., Defendant and Counterclaim Plaintiff.	Civil Action No. 2:10-cv-00128-RBS-FBS

TEVA PHARMACEUTICALS USA, INC.'S
REVISED FIRST AMENDED ANSWER AND COUNTERCLAIM

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") hereby responds to Pfizer Inc.'s, Pfizer Limited's and Pfizer Ireland Pharmaceuticals' (collectively, "Pfizer") Complaint ("the Complaint") as follows:

Nature of the Action

1. No response is required from Teva USA to the extent that the allegations in Paragraph 1 of the Complaint are directed to Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), or to the extent that Paragraph 1 states conclusions of law. Teva USA admits that Pfizer asserts that this patent infringement action relates to Teva USA's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, sale and/or importation of 25 mg, 50 mg and 100 mg sildenafil citrate tablets. Teva USA denies the remaining allegations in Paragraph 1.

The Parties

2. Upon information and belief, Teva USA admits that Pfizer Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 235 East 42nd Street, New York, New York. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 2 of the Complaint and therefore denies the same.

3. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3 of the Complaint and therefore denies the same.

4. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 4 of the Complaint and therefore denies the same.

5. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 5 of the Complaint and therefore denies the same.

6. Teva USA admits that it is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

7. No response is required from Teva USA because the allegations in Paragraph 7 of the Complaint are directed solely to Teva Ltd.

8. No response is required from Teva USA to the extent that the allegations in Paragraph 8 of the Complaint are directed to Teva Ltd. Teva USA admits that it is an indirect wholly-owned subsidiary of Teva Ltd.

Jurisdiction and Venue

9. No response is required from Teva USA to the extent that the allegations in Paragraph 9 of the Complaint are directed to Teva Ltd. or state conclusions of law. To the extent that the allegations in Paragraph 9 of the Complaint are directed to Teva USA, Teva USA admits that Pfizer purports to bring this action under the Patent Laws of the United States. Teva USA further admits that Pfizer bases jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. No response is required from Teva USA to the extent that the allegations in Paragraph 10 of the Complaint are directed to Teva Ltd. To the extent that the allegations in Paragraph 10 are directed to Teva USA, Teva USA admits, for purposes of this action only, that venue with respect to Teva USA is proper in this judicial district under 28 U.S.C. § 1391.

11. Teva USA, for purposes of this action only, admits that this Court has personal jurisdiction over Teva USA. No response is required from Teva USA to the extent that Paragraph 11 of the Complaint states conclusions of law. Teva USA denies the remaining allegations in Paragraph 11 of the Complaint.

12. No response is required from Teva USA because the allegations in Paragraph 12 of the Complaint are directed solely to Teva Ltd.

Background

The '012 Patent

13. Teva USA admits that according to the face of U.S. Patent No. 6,469,012 ("the '012 patent"), the '012 patent is titled "Pyrazolopyrimidinones for the Treatment of Impotence," and that it issued on October 22, 2002. Teva USA also admits that according to the face of the '012 patent, the '012 patent issued to Pfizer, Inc. as the assignee of Peter Ellis and Nicholas

Kenneth Terrett. Teva USA admits that the United States Patent and Trademark Office ("PTO") has reexamined the '012 patent, and that claims 1-23, 25 and 26 remain in the '012 patent. Teva USA admits that the PTO found that the subject matter described in claim 24 of the '012 patent is not patentable. Teva USA further admits that what appears to be a copy of the '012 patent is attached to the Complaint as Exhibit A.

14. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 14 of the Complaint and therefore denies the same.

15. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 15 of the Complaint and therefore denies the same.

Orange Book Listing for VIAGRA®

16. No response is required from Teva USA to the extent that the allegations in Paragraph 16 of the Complaint state conclusions of law. Teva USA admits that the FDA's Electronic Orange Book identifies "Pfizer Ireland" as the company that submitted New Drug Application No. 20-895 for Viagra®. Upon information and belief, Teva USA admits that Pfizer markets commercial formulations of sildenafil citrate under the trade name Viagra®. Teva USA also admits that the Electronic Orange Book identifies the '012 patent as purportedly covering Viagra®. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 16 of the Complaint and therefore denies the same.

17. Teva USA admits that the FDA's Electronic Orange Book identifies the expiration date of the '012 patent as October 22, 2019.

18. Teva USA admits that the FDA's Electronic Orange Book identifies U.S. Patent No. 5,250,534 ("the '534 patent") as purportedly covering Viagra®, and identifies the expiration date of the '534 patent as March 27, 2012.

Teva's ANDA

19. Teva USA admits that Teva USA sent a letter to Pfizer Inc. and Pfizer Ireland on or about December 17, 2004, notifying Pfizer Inc. and Pfizer Ireland that Teva USA had submitted ANDA No. 77-342 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale and/or importation of the products identified in ANDA No. 77-342 by Teva USA ("Teva's ANDA Products").

20. Teva USA admits that Teva USA's December 17, 2004 letter stated the factual and legal bases for Teva USA's opinion that the '012 patent is invalid, unenforceable and not infringed by the manufacture, use, or sale of Teva's ANDA Products.

21. No response is required from Teva USA to the extent that the allegations in Paragraph 21 of the Complaint are directed to Teva Ltd. Teva USA admits that it caused ANDA No. 77-342 to be submitted to the FDA. Teva USA denies the remaining allegations in Paragraph 21 of the Complaint.

22. Teva admits that the FDA granted tentative approval for ANDA No. 77-342 on April 24, 2007.

23. No response is required from Teva USA to the extent that the allegations in Paragraph 23 of the Complaint are directed to Teva Ltd. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 23 of the Complaint and therefore denies same.

COUNT I
(Patent Infringement)

24. Teva USA repeats and incorporates herein by reference its responses to Paragraphs 1-23 of the Complaint.

25. No response is required from Teva USA to the extent that the allegations in Paragraph 25 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 25 states conclusions of law. To the extent that the allegations in Paragraph 25 are directed to Teva USA, Teva USA denies the same.

26. No response is required from Teva USA to the extent that the allegations in Paragraph 26 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 26 states conclusions of law. Teva USA admits that it was aware of the '012 patent at the time it submitted ANDA No. 77-342 to the FDA.

27. No response is required from Teva USA to the extent that the allegations in Paragraph 27 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 27 states conclusions of law. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegation in Paragraph 27 of the Complaint that Teva USA intends to engage in the manufacture, use, offer for sale, sale, and/or importation of its ANDA Products with the proposed labeling immediately upon expiration of the '534 patent on March 27, 2012, and therefore denies the same. Teva USA denies the remaining allegations in Paragraph 27 of the Complaint.

28. No response is required from Teva USA to the extent that the allegations in Paragraph 28 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 28 states conclusions of law. To the extent that the allegations in Paragraph 28 are directed to Teva USA, Teva USA denies the same.

29. No response is required from Teva USA to the extent that the allegations in Paragraph 29 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 29 states

conclusions of law. To the extent that the allegations in Paragraph 29 are directed to Teva USA, Teva USA denies the same.

30. No response is required from Teva USA to the extent that the allegations in Paragraph 30 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 30 states conclusions of law. To the extent that the allegations in Paragraph 30 are directed to Teva USA, Teva USA denies the same.

31. No response is required from Teva USA to the extent that the allegations in Paragraph 31 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 31 states conclusions of law. To the extent that the allegations in Paragraph 31 are directed to Teva USA, Teva USA denies the same.

32. No response is required from Teva USA to the extent that the allegations in Paragraph 32 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 32 states conclusions of law. To the extent that the allegations in Paragraph 32 are directed to Teva USA, Teva USA denies the same.

COUNT II
(Declaratory Judgment of Infringement)

33. Teva USA repeats and incorporates herein by reference its responses to Paragraphs 1-32 of the Complaint.

34. No response is required from Teva USA to the extent that the allegations in Paragraph 34 of the Complaint are directed to Teva Ltd. Teva USA admits that Pfizer asserts its Count II under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Teva USA admits that there is an actual controversy between Pfizer and Teva USA.

35. No response is required from Teva USA to the extent that the allegations in Paragraph 35 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 35 states

conclusions of law or background information rather than allegations. Teva USA denies the remaining allegations in Paragraph 35 of the Complaint.

36. No response is required from Teva USA to the extent that the allegations in Paragraph 36 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 36 states conclusions of law. Teva USA lacks knowledge or information sufficient to form a belief about the truth of the allegation in Paragraph 36 of the Complaint that Teva USA intends to engage in the manufacture, use, offer for sale, sale, and/or importation of its ANDA Products with the proposed labeling immediately upon expiration of the '534 patent on March 27, 2012, and therefore denies same. Teva USA denies the remaining allegations in Paragraph 36 of the Complaint.

37. No response is required from Teva USA to the extent that the allegations in Paragraph 37 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 37 states conclusions of law. To the extent that the allegations in Paragraph 37 are directed to Teva USA, Teva USA denies the same.

38. No response is required from Teva USA to the extent that the allegations in Paragraph 38 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 38 states conclusions of law. To the extent that the allegations in Paragraph 38 are directed to Teva USA, Teva USA denies the same.

39. No response is required from Teva USA to the extent that the allegations in Paragraph 39 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 39 states conclusions of law. To the extent that the allegations in Paragraph 39 are directed to Teva USA, Teva USA denies the same.

40. No response is required from Teva USA to the extent that the allegations in Paragraph 40 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 40 states conclusions of law. To the extent that the allegations in Paragraph 40 are directed to Teva USA, Teva USA denies the same.

41. No response is required from Teva USA to the extent that the allegations in Paragraph 41 of the Complaint are directed to Teva Ltd., or to the extent that Paragraph 41 states conclusions of law. To the extent that the allegations in Paragraph 41 are directed to Teva USA, Teva USA denies the same.

42. Teva USA further answers that any allegations in the Complaint requiring a response from Teva USA that are not specifically admitted are denied, and that no response is required from Teva USA to the extent that the allegations in the Complaint are directed to Teva Ltd. Teva USA also denies that Pfizer is entitled to the judgment and relief prayed for in Paragraphs A through G of the Complaint.

TEVA USA'S AFFIRMATIVE DEFENSES

First Affirmative Defense

43. The Complaint fails to state a claim upon which relief can be granted.

Second Affirmative Defense

44. The manufacture, use, offer for sale, sale or importation of the sildenafil citrate products specified in ANDA No. 77-342 does not and will not infringe any valid and enforceable claim of the '012 patent, either literally or under the doctrine of equivalents.

Third Affirmative Defense

45. The claims of the '012 patent are invalid under 35 U.S.C. §§ 101 *et seq.*, including §§ 102, 103 and 112.

Fourth Affirmative Defense

46. Each of the claims of the '012 patent is unenforceable because the applicants for the '012 patent, including at least one of the named inventors and Pfizer legal representatives, engaged in inequitable conduct during the prosecution of the application for the '012 patent, and during the reexamination of the '012 patent in the PTO. The specific acts and circumstances that constitute inequitable conduct are set forth with particularity below in Paragraphs 15–61 of Teva USA's Counterclaim for Declaratory Judgment, and are incorporated by reference herein as the bases for Teva USA's inequitable conduct defense.

47. Teva USA specifically reserves the right to assert each and every other defense that may become evident in the course of discovery.

COUNTERCLAIM FOR DECLARATORY JUDGMENT

Counterclaim-Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva USA"), for its counterclaim against Counterclaim-Defendants Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer"), alleges as follows:

Nature of the Action

1. Teva USA incorporates by reference Paragraphs 1–41 set forth above.

2. This is an action for a judgment declaring that claim 25 and claim 26 of the '012 patent are invalid, that the '012 patent is unenforceable, and that Teva USA has not infringed and will not infringe claim 25 or claim 26 of the '012 patent, either directly, or by inducing or contributing to infringement by others, by engaging in the commercial manufacture, use, sale, offer for sale and/or importation of Teva's ANDA Products. A copy of the '012 patent is attached to Pfizer's Complaint.

The Parties

3. Counterclaim-Plaintiff Teva USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. Counterclaim-Defendant Pfizer Inc. has averred that it is a corporation organized under the laws of the State of Delaware, with its principal place of business at 235 East 42nd Street, New York, New York.

5. Counterclaim-Defendant Pfizer Limited has averred that it is a corporation organized under the laws of England, with its principal place of business at Ramsgate Road, Sandwich, Kent, England.

6. Counterclaim-Defendant Pfizer Ireland Pharmaceuticals has averred that it is a partnership existing pursuant to the laws of Ireland, with its registered office at Pottery Road, Dun Laoghaire, County Dublin, Republic of Ireland.

Jurisdiction and Venue

7. This Counterclaim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. This Court has subject matter jurisdiction over this Counterclaim under 28 U.S.C. §§ 1331, 1338(a), 2201(a) and 2202.

9. The Counterclaim-Defendants submitted to the personal jurisdiction of this Court by filing their Complaint in this action.

10. Venue is proper in this Judicial District under 28 U.S.C. § 1391(b)-(d).

The Existence of an Actual Controversy

11. Counterclaim-Defendants' allegations of patent infringement against Teva USA in this action created an actual controversy between Teva USA and Pfizer regarding the validity, infringement and enforceability of each claim of the '012 patent. On December 6, 2010, Counterclaim-Defendants provided to Teva USA a document titled "Covenant Not To Sue," which states that Counterclaim-Defendants covenant "not to sue or otherwise hold TEVA PHARMACEUTICALS USA, INC, its parents, subsidiaries and/or affiliated companies … liable for direct infringement, induced infringement and/or contributory infringement under Claims 1-23 of the '012 Patent …." Notwithstanding Counterclaim-Defendants' December 6, 2010 Covenant Not To Sue, there remains an actual controversy between Teva USA and Pfizer regarding the validity, infringement and enforceability of claim 25 and claim 26 of the '012 patent.

12. Counterclaim-Defendant Pfizer Inc. has averred that it is an assignee of the '012 patent. Counterclaim-Defendant Pfizer Limited has averred that it is the owner of a beneficial interest in the '012 patent. Counterclaim-Defendant Pfizer Ireland Pharmaceuticals has averred that it is an exclusive licensee under the '012 patent. Counterclaim-Defendants Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals have averred that they have all right, title and interest in the '012 patent, including the right to sue for infringement thereof. The '012 patent is titled "Pyrazolopyrimidinones for the Treatment of Impotence," and the patent states on its face that it issued on October 22, 2002.

Non-infringement and Invalidity

13. Teva USA has not infringed, contributed to the infringement of, or induced the infringement of, and will not infringe, contribute to the infringement of, or induce the infringement of claim 25 or claim 26 of the '012 patent. The commercial manufacture, use, sale, offer for sale or importation of Teva's ANDA Products identified in ANDA No. 77-342 by Teva USA after it obtains approval from the FDA for those products, would not directly infringe, contribute to the infringement of or induce the infringement of claim 25 or claim 26 of the '012 patent.

14. Claim 25 and claim 26 of the '012 patent are invalid for failure to comply with the Patent Laws of the United States, including the conditions and requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including §§ 102, 103 and 112.

Unenforceability Due to Inequitable Conduct

Introduction

15. Each of the claims of the '012 patent is unenforceable because the applicants for the '012 patent, together with their attorneys and agents, and others associated with, or

substantively involved in the prosecution of the application that led to the issuance of the '012 patent ("'012 patent prosecution"), engaged in inequitable conduct during the '012 patent prosecution. Those individuals prosecuted claims directed to treating erectile dysfunction in a "male animal" in bad faith, knowing that they were overbroad and unpatentable. They also withheld from the PTO highly material information about their knowledge of the overbreadth of those "animal" claims. Those individuals engaged in further inequitable conduct during the subsequent reexamination of the '012 patent ("'012 patent reexamination") by continuing to assert the validity of the "animal" claims in those proceedings from 2003 until November 2, 2010 (when the PTO's reexamination certificate issued), even though Pfizer disclaimed nearly identical subject matter in a related Canadian patent in 2002, just 17 days after the '012 patent issued in the United States. Co-inventor Peter Ellis explained later in a declaration submitted to a court in Canada that Pfizer filed that disclaimer because the word "animal" was "much too broad in scope," "the wrong word to describe the scope of what was scientifically predictable," and "a mistake." The applicants attempted to conceal from the PTO the reasons for filing the disclaimer in Canada by withholding and burying documents that discussed the substance of the disclaimer throughout the lengthy '012 patent reexamination. Through their bad faith prosecution and acts of concealment, the applicants obtained the overbroad claims of the '012 patent directed to animals (*i.e.*, claims 1–19 and 21–23), and prevented the PTO from noting and making it a matter of public record that the "animal" claims are overbroad and invalid. As more fully described in the paragraphs below, the applicants for the '012 patent breached their duties of candor and good faith to the PTO (37 C.F.R. § 1.56(a)) with deceptive intent. That inequitable conduct renders each of the claims of the '012 patent unenforceable.

The Canadian Disclaimer

16. On July 7, 1998, Pfizer Research and Development Company, N.V./S.A. ("Pfizer R&D"), a Pfizer Inc. subsidiary, obtained Canadian Patent No. 2,163,446, titled "Pyrazolopyrimidinones for the Treatment of Impotence" ("the '446 patent"). The '446 patent and the '012 patent are both national stage filings of PCT International Application No. PCT/EP94/28902 ("the '902 international application"), which was filed on May 13, 1994 and claims priority[1] of Great Britain Patent Application No. 9311920, filed June 9, 1993. Like the '012 patent and the '902 international application, the Canadian counterpart '446 patent names Drs. Peter Ellis and Nicholas Kenneth Terrett as inventors.

17. The claims of the Canadian counterpart '446 patent currently are limited to the treatment of erectile dysfunction in "man" (using, *e.g.*, sildenafil citrate). The '446 patent originally issued, however, with much broader claims that covered the treatment of erectile dysfunction in a "male animal." Specifically, claims 1–7, 10–13, 16, 17, 20–24 of the '446 patent, as originally issued, were directed to uses, compositions, processes for preparing compositions, and commercial packages relating to the treatment of erectile dysfunction in a "male animal" or sexual dysfunction in a "female animal." Claims 8, 9, 14, 15, 18, 19 and 25–27 on the other hand, limited such uses, compositions and processes to treatment of erectile dysfunction in "man" and sexual dysfunction in "woman" (*i.e.*, limited to humans).

18. On June 5, 2002 – while the application for the '012 patent was pending in the PTO in the United States, and more than four months before the '012 patent issued – Bayer AG

[1] Under the right of "priority," a United States patent application is entitled to the benefit of the filing date of an earlier filed foreign patent application for purposes of overcoming an intervening reference or for similar purposes, provided that certain conditions and requirements specified in 35 U.S.C. § 119(a)–(d) and (f) and 37 C.F.R. § 1.55 are met. M.P.E.P. § 201.13 (8th ed. 2010). A United States patent application may be entitled to the right of priority based on a prior filed international application, and an international application may be entitled to the right of priority based on a prior foreign application. 35 U.S.C. § 365(a), (b).

and Bayer Inc. (collectively, "Bayer") filed a lawsuit against Pfizer R&D ("Canadian Case No. T-865-02") seeking a declaration from the Canadian Federal Court that the claims of the '446 patent directed to the treatment of erectile dysfunction and sexual dysfunction in animals were invalid because they were overbroad. In ¶ 18(2) of its June 5, 2002 Statement of Claim, Bayer asserted that the subject matter described in the claims of the '446 patent concerning the treatment of erectile dysfunction in male animals was broader than what the inventors had invented and broader than the disclosure in the specification of the patent:

> (2) As to claims 1 to 27, they are directed to or include use of the specified compounds for the curative and prophylactic treatment of a male animal including man and/or the curative or prophylactic treatment of sexual dysfunction in a female animal including woman, or compositions, commercial packages or processes related to such treatment and as such are broader than the alleged invention made by the named inventors and broader than the alleged invention described in the specification. There is no disclosure in the specification of any respect in which "the compounds of the invention" could be used for the curative or prophylactic treatment of erectile dysfunction in a male animal or sexual dysfunction in a female animal.

19. Pfizer R&D acquiesced, and responded to Bayer's allegations of overbreadth by disclaiming the subject matter in the claims of the '446 patent directed to non-human animals.

20. Specifically, on November 8, 2002 – only 17 days after the PTO granted the '012 patent in the United States – Pfizer R&D signed a document titled "Disclaimer with Respect to Canadian Patent No. 2,163,446" ("Canadian Disclaimer"), in which Pfizer R&D disclaimed all subject matter in the claims of the '446 patent relating to the treatment of erectile dysfunction or sexual dysfunction in non-human animals.

21. The Canadian Disclaimer states in pertinent part:

> 1. The patentee of Patent No. 2,163,446, granted on July 7, 1998 for an invention entitled Pyrazolopyrimidinones for the

> Treatment of Impotence, has, by mistake, accident or inadvertence, and without any wilful intent to defraud or mislead the public,
>
> a) made the specification too broad, claiming more than that of which the patentee or person through whom the patentee claims was the inventor, or
>
> b) in the specification, claimed that the patentee or person through whom the patentee claims was the inventor of any material or substantial part of the invention patented of which the patentee was not the inventor, and to which the patentee had no lawful right.

22. Andrew I. McIntosh of Bereskin & Parr, Pfizer R&D's outside patent counsel, filed the Canadian Disclaimer with the Canadian Intellectual Property Office ("CIPO") on November 14, 2002. Before they filed the Canadian Disclaimer, attorneys at Bereskin & Parr consulted with Dr. Ellis about the subject matter of the Canadian Disclaimer.

23. Through its Canadian Disclaimer, Pfizer R&D narrowed claims 1–5, 7, 10–13, 20 and 21 of the '446 patent to limit them to uses, compositions, processes for preparing compositions, and commercial packages directed to the treatment of erectile dysfunction in "man" or sexual dysfunction in "woman" (*i.e.*, that disclaimer limited the scope of those claims to humans). Counterclaim Defendant Pfizer Ireland Pharmaceuticals ("Pfizer Ireland"), a Pfizer Inc. subsidiary and successor in interest of the '446 patent, later disclaimed all subject matter in the claims of the '446 patent concerning the treatment of sexual dysfunction in females, so that the claims of the '446 patent currently are limited to uses, compositions, processes for preparing compositions, and commercial packages directed to the treatment of erectile dysfunction in male humans.

24. According to Pfizer's Dr. Ellis, the November 2002 Canadian Disclaimer was necessary because claims directed to the treatment of erectile or sexual dysfunction in animals were overbroad and not patentable. Specifically, on October 4, 2005, in connection with a

lawsuit involving the '446 patent in Canadian Federal Court ("Canadian Case No. T-1314-05"), Dr. Ellis signed a sworn affidavit ("Ellis Affidavit") in which he candidly explained that the reason for filing the Canadian Disclaimer was that the claim term "animal" "was the wrong word to describe the scope of what was scientifically predictable," was "much too broad in scope," and that "[i]t was a mistake" that he "simply overlooked … at the time we filed the patent."

25. In particular, ¶¶ 59 and 60 of the Ellis Affidavit state:

> 59. On June 9, 1993, when we filed the original provisional application we included a paragraph on page 7 and 8 for use of the compound in a male animal for veterinary use and made the claims broad enough to include a male animal. We had not by that date done testing to show that an animal, other than [a] human suffering from erectile dysfunction, would benefit from the use of sildenafil or other cGMP PDE inhibitor. We did know, however, that many male animals have penises, which are similar in operation to that of a human, and it seemed reasonable from a scientific point of view to predict that this treatment would work in them as well as in men. The word "animal", however, was the wrong word to describe the scope of what was scientifically predictable. The term "Animal" includes a variety of living creatures such as mammals, birds, reptiles and insects. It is much too broad in scope. I simply overlooked this at the time we filed the patent. It was a mistake.
>
> 60. This mistake was corrected in the first disclaimer. All reference to animals was deleted from the claims.

Inequitable Conduct During the '012 Patent Prosecution

26. Notwithstanding Pfizer R&D's disclaimer of the non-human animal subject matter in the claims of the Canadian '446 patent because the term "animal" was "much too broad in scope," and notwithstanding, upon information and belief, Dr. Ellis's knowledge about the Canadian Disclaimer during the pendency of the application for the '012 patent in the United States, Dr. Ellis and Counterclaim Defendant Pfizer Inc. (Pfizer R&D's parent company), through Pfizer Inc.'s patent counsel, including at least internal counsel Gregg C. Benson and James T. Jones, and external counsel Gerard M. O'Rourke and perhaps others at Connolly, Bove,

Lodge & Hutz (collectively, "Applicants"), sought and ultimately obtained claims from the PTO directed to methods of treating erectile dysfunction in animals without any limitations to humans (using, *e.g.*, sildenafil citrate). Specifically, claims 1–19 and 21–23 of the '012 patent ("animal claims") are directed to methods of treating erectile dysfunction in a "male animal." Claim 2 is expressly limited to veterinary treatment.

27. The '012 patent also includes claims 20, 25 and 26, which are directed more narrowly to methods of treating erectile dysfunction in a "male human."

28. Teva believes on the basis of the information set forth below that the Applicants were aware that the claims they were prosecuting in the application for the '012 patent directed to animals and containing subject matter concerning non-human animals were overbroad and unpatentable before the PTO issued the '012 patent in the United States.

29. Pfizer R&D and its counsel responded to Bayer's June 5, 2002 overbreadth allegations on September 10, 2002, more than six weeks before the '012 patent issued. Specifically, on September 10, 2002, Pfizer R&D, through its counsel Bereskin & Parr, filed a Statement of Defense in response to Bayer's Statement of Claim. Attorneys Robert H.C. MacFarlane, Michael E. Charles and Andrew McIntosh of Bereskin & Parr signed Pfizer's Statement of Defense. Pfizer R&D signed the Canadian Disclaimer on November 8, 2002, a mere 17 days after the '012 patent issued in the United States on October 22, 2002. Bayer's December 5, 2002 Reply noted that the Canadian Disclaimer constituted an "admission" by Pfizer R&D that the claims of the '446 patent as issued were "broader than the alleged invention made by the named inventors."

30. Dr. Ellis consulted with Pfizer R&D's counsel, including at least attorneys at Bereskin & Parr, about the subject matter of, and purpose for, the Canadian Disclaimer before the Applicants filed it in Canada on November 15, 2002.

31. Upon information and belief, Counterclaim Defendant Pfizer Inc.'s U.S. patent counsel also knew during the '012 patent prosecution of Bayer's explicit allegations that Pfizer R&D's Canadian patent claims directed to animals were overbroad and unpatentable. Upon information and belief, in at least 2001 and 2002, Pfizer Inc.'s U.S. patent counsel regularly received documents from foreign patent opposition proceedings and lawsuits related to the '012 patent, including those related to the Canadian '446 patent, from Counterclaim Defendant Pfizer Limited's patent department. In that regard, on March 1, 2002, Lilly ICOS LLC and Eli Lilly Canada Inc. (collectively, "Lilly") filed a lawsuit against Pfizer R&D in Canadian Federal Court alleging that the '446 patent was invalid. Six days later, on March 7, 2002, Pfizer R&D's Canadian counsel at Smart & Biggar forwarded a copy of Lilly's allegations to Pfizer Limited's patent department in the United Kingdom. Eleven days later, on March 18, 2002, Watson P. McMunn of Pfizer Limited's patent department forwarded those allegations to Mr. O'Rourke, Pfizer Inc.'s outside patent counsel in the United States, who was substantively involved in the '012 patent prosecution. Similarly, on June 12, 2002, a week after Bayer filed its allegations in Canadian Case No. T-865-02, Pfizer R&D's Canadian counsel at Smart & Biggar forwarded Mr. McMunn a copy of those allegations. Upon information and belief, prior to the issuance of the '012 patent, Mr. McMunn forwarded Bayer's Canadian allegations to Mr. O'Rourke in the United States.

32. The Applicants routinely disclosed documents relating to foreign patent opposition proceedings and lawsuits to the PTO during the '012 patent prosecution. In 2001, for

example, the Applicants filed several Information Disclosure Statements, signed by Pfizer Inc.'s outside counsel Mr. O'Rourke, that disclosed and described documents from opposition proceedings and lawsuits from foreign jurisdictions, including the European Patent Office, the United Kingdom, Israel, the Netherlands, Belgium, Chile, Japan and China.

33. The Applicants, however, did not disclose or describe to the PTO any information about Canadian Case No. T-865-02 during the '012 patent prosecution. The Applicants did not notify the PTO during the '012 patent prosecution of Bayer's allegations that the claims of the '446 patent directed to treating erectile dysfunction in animals were invalid because those claims were "broader than the alleged invention described in the specification." Meanwhile, in Canada, Pfizer R&D responded to those allegations by disclaiming the non-human animal subject matter in the claims of the '446 patent.

34. Several years before Bayer even alleged that Pfizer R&D's Canadian claims directed to animals were overbroad, the Applicants already appreciated the underlying "mistake" acknowledged in the Ellis Affidavit – *i.e.*, that although "many male animals have penises," it does not mean that it was "reasonable from a scientific point of view to predict that [the claimed] treatment would work" in all non-human animals. In fact, during the '012 patent prosecution, the Applicants repeatedly relied on a distinction between the anatomy and physiology of human and bovine penises to overcome an obviousness rejection.

35. More specifically, on February 10, 1998, the Applicants filed a response to an August 12, 1997 Final Office Action from the PTO that rejected the claims in the application for the '012 patent as obvious over, *inter alia*, a prior art reference that disclosed experiments in which the compound zaprinast, a PDE5 inhibitor, was employed in bovine retractor penis muscle and found to cause a selective 3–4 fold elevation of cGMP in the muscle ("the Bowman article").

In their response to that rejection, the Applicants dismissed the Bowman article as irrelevant because humans, unlike cattle, oxen and other bovines, do not have retractor penises and the retractor penis muscle has no role in human penile erection. On page 18 of their response, the Applicants stated:

> First, it is noted that the retractor penis muscle has no role in penile erection in humans (as supported by the first Rule 132 Declaration included herewith, see paragraph 7). Thus, one looking for a cure for sexual dysfunction in humans would undoubtedly dismiss Bowman out of hand as irrelevant.

36. The Applicants submitted with their February 10, 1998 response a First Declaration Under 37 C.F.R. § 1.132 signed by a Pfizer researcher named Stephen A. Ballard ("Ballard Declaration"), which explained that retractor penis muscles such as those in bovine retractor penises, which function by protrusion, do not play a role in human penile erections, which are based on rigidity:

> 7. Bowman reported work related to the mediation of neurogenic relaxation in bovine retractor penis muscle, and reported conducting experiments wherein zaprinast was stated to relax the muscle, potentiate an inhibitory response [*sic*] to nerve stimulation, and cause a rise in the cyclic GMP content of the tissue. Protrusion of the penis (but not rigidity) in some animals may be aided by relaxation of the retractor penis muscle. The retractor penis muscle does not play a role in human penile erection, however, and thus a scientist working in this area would not conclude from the Bowman article that there is a reasonable expectation of success relating to the treatment of human sexual dysfunction with cGMP PDE_V inhibitors.

37. In their subsequent August 4, 1998 Brief of Appellants Under 37 C.F.R. § 1.192 (a), the Applicants repeated their February 10, 1998 arguments to the PTO about the Bowman article nearly verbatim.

38. Notwithstanding repeated arguments to the PTO that the penises in male animals are not the same and do not function the same way, the Applicants continued to prosecute and ultimately obtained allowance of claims directed broadly to the treatment of erectile dysfunction in a "male animal," and other claims directed more narrowly to the treatment of erectile dysfunction in a "male human."

39. The Applicants, including Dr. Ellis, Counterclaim Defendant Pfizer Inc. and Pfizer Inc.'s patent counsel, including at least Messrs. Benson, Jones, and O'Rourke and perhaps others at Connolly, Bove, Lodge & Hutz, owed the PTO a duty of candor and good faith in connection with the '012 patent prosecution. On February 27, 1996, Dr. Ellis executed a Combined Declaration for Patent Application and Power of Attorney in connection with the application for the '012 patent ("Inventors' Declaration"), in which he stated that he had reviewed and understood the contents of the specification, including the claims, as amended by preliminary amendment and during international preliminary examination. The Applicants submitted the Inventors' Declaration to the PTO on March 4, 1996. By signing the Inventors' Declaration, Dr. Ellis explicitly acknowledged his duty to disclose to the PTO information that is material to the examination of the application for the '012 patent in accordance with 37 C.F.R. § 1.56(a).

40. The Inventors' Declaration also appointed several attorneys, including Messrs. Benson and Jones, to prosecute the application for the '012 patent and transact all business with the PTO connected therewith. The Inventors' Declaration further specified that correspondence should be sent to Mr. Benson, and that telephone calls should be directed to Mr. Jones. Later during prosecution, Mr. Jones submitted an Associate Power of Attorney for Mr. O'Rourke, an attorney at Connolly, Bove, Lodge & Hutz. Upon information and belief, Mr. Jones signed

nearly all of the communications sent to the PTO during the course of the ‘012 patent prosecution and participated in several substantive telephone conferences with the PTO Examiner; Mr. Benson, Mr. Jones’ colleague, was the recipient of all written communications from the PTO regarding the application for the ‘012 patent; and Mr. O’Rourke filed several information disclosure statements disclosing documents from related foreign proceedings. Each of those individuals was substantively involved in the ‘012 patent prosecution and owed a duty of candor and good faith to the PTO during the ‘012 patent prosecution.

41. By prosecuting and ultimately obtaining the allowance of claims directed to methods of treating erectile dysfunction in male animals, the Applicants effectively asserted that they were entitled to those claims, and that those claims meet the statutory requirements of patentability. Upon information and belief, however, the Applicants knew before the issuance of the ‘012 patent that the pending claims directed to methods of treating erectile dysfunction in male animals were “much too broad in scope” and did not meet the statutory requirements of patentability. The Applicants prosecuted the claims directed to animals in the application for the ‘012 patent in the PTO in bad faith.

42. The Applicants’ knowledge that the claims directed to treating erectile dysfunction in male animals were “much too broad in scope” and did not meet the statutory requirements of patentability was highly material to the patentability of the claims directed to animals in the application for the ‘012 patent. The Applicants did not disclose that information to the PTO during the ‘012 patent prosecution.

43. The Applicants, including at least Dr. Ellis and Messrs. Benson, Jones and O’Rourke, breached their duties of candor and good faith with intent to deceive the PTO by failing to disclose that the pending claims directed to treating erectile dysfunction in male

animals were "much too broad in scope" and did not meet the statutory requirements of patentability.

44. Because Pfizer R&D filed the Canadian Disclaimer in response to Bayer's allegations in Canadian Case No. T-865-02, that case (including Bayer's allegation that the claims of the '446 patent directed to animals were overbroad and invalid) was highly material to the patentability of the claims directed to animals in the application for the '012 patent.

45. Upon information and belief, the Applicants, including at least Dr. Ellis and Messrs. Benson, Jones and O'Rourke, breached their duties of candor and good faith with intent to deceive the PTO by failing to disclose Canadian Case No. T-865-02 (including Bayer's allegation that the claims of the '446 patent directed to animals were overbroad and invalid) to the PTO during the '012 patent prosecution.

46. Upon information and belief, the omissions and misleading conduct described in Paragraphs 15–45 above were highly material to the decision of the PTO to issue the '012 patent. A reasonable examiner would have considered the information withheld by the Applicants important in deciding whether to allow the application for the '012 patent to issue.

47. The '012 patent is unenforceable because the Applicants failed to satisfy the duty of candor and good faith under 37 C.F.R. § 1.56(a) during the prosecution of the '012 patent. Their highly material omissions and misleading conduct during the '012 patent prosecution constitutes inequitable conduct that renders the '012 patent unenforceable. As described in Paragraphs 15–46 above, those highly material omissions and that misleading conduct include (i) the Applicants' prosecution and ultimate receipt of claims directed to the treatment of erectile dysfunction in male animals (claims 1–19 and 21–23 of the '012 patent), despite their knowledge that such subject matter was "much too broad" and beyond "the scope of what was scientifically

predictable," (ii) the Applicants' failure to disclose to the PTO that claims directed to treating erectile dysfunction in male animals were "much too broad in scope" and did not meet the statutory requirements of patentability, and (iii) the Applicants' failure to disclose to the PTO the existence of Canadian Case No. T-865-02 and Bayer's June 5, 2002 allegations therein that the claims of the '446 patent covering the treatment of erectile dysfunction in animals were overbroad and invalid. Upon information and belief, the Applicants, including at least Dr. Ellis and Messrs. Benson, Jones and O'Rourke, acted with deceptive intent to secure broad claims directed to the use of sildenafil citrate to treat erectile dysfunction in any animal, claims to which the Applicants knew they were not entitled.

Inequitable Conduct During Reexamination of the '012 Patent

48. The PTO initiated a proceeding to reexamine the '012 patent on September 22, 2003, at which time the PTO reopened prosecution to examine the validity of claims 1–26 of the '012 patent. The reexamination proceeding commenced by the PTO was consolidated with three other reexaminations of the '012 patent commenced later at the request of third parties. On May 10, 2010, more than six and a half years later, the PTO mailed a Notice of Intent to Issue Ex Parte Reexamination Certificate, which effectively closed prosecution on the merits in the consolidated '012 patent reexamination proceedings. The PTO issued a Reexamination Certificate on November 2, 2010.

49. Dr. Peter Ellis owed a duty of candor and good faith to the PTO in connection with each of the '012 patent reexamination proceedings.

50. While the '012 patent reexamination proceedings were pending, Dr. Ellis knew that the '012 patent was the subject of reexamination, and he was directly involved in those reexamination proceedings. Pfizer Inc. submitted to the PTO in 2005 two declarations signed by

Dr. Ellis on March 29, 2005 and November 11, 2005. On October 4, 2005 – approximately five weeks before Dr. Ellis executed his November 11, 2005 declaration – Dr. Ellis signed the Ellis Affidavit in Canada explaining that Pfizer disclaimed the animal claims in Canada because they were far too broad and were not patentable. Dr. Ellis failed, however, to advise the PTO about the subject matter of the Canadian Disclaimer, or about ¶¶ 59 or 60 of the Ellis Affidavit in either of his 2005 reexamination declarations, or at any other time during the '012 patent reexamination. Upon information and belief, Dr. Ellis never told the PTO during the '012 patent reexamination that he knew that the animal claims in the '012 patent are overbroad, or that the term "animal" is "much too broad in scope," "the wrong word to describe the scope of what was scientifically predictable," and "a mistake."

51. Pfizer Inc. and the Pfizer Inc. patent lawyers who were substantively involved in the '012 patent reexamination, including at least Gregg C. Benson and James T. Jones (collectively, "Patentees"), also owed duties of candor and good faith to the PTO at all times during the '012 patent reexamination proceedings. Mr. Jones signed most of Pfizer Inc.'s substantive submissions in the '012 patent reexamination. Upon information and belief, Mr. Benson, Mr. Jones' colleague, was the recipient of all communications from the PTO to Pfizer Inc. during the '012 patent reexamination.

52. Upon information and belief, the Patentees were aware, during the '012 patent reexamination, of the discrepancy between the claims of the '012 patent in the United States and the claims of the counterpart '446 patent in Canada, *i.e.*, that (a) Pfizer R&D has disclaimed the subject matter in the Canadian '446 patent directed to non-human animals because the claims were overbroad and unpatentable, and (b) the United States '012 patent nevertheless includes

animal claims (claims 1–19 and 21–23) that cover subject matter explicitly directed to non-human animals.

53. Upon information and belief, the Patentees never canceled the animal claims in the ‘012 patent or otherwise disclaimed the subject matter in those animal claims directed to non-human animals, even though the Patentees knew of the discrepancy described in Paragraph 52 above.

54. Upon information and belief, the Patentees never affirmatively informed the PTO that the animals claims in the ‘012 patent are overbroad or that the term “animal” is “much too broad in scope,” “the wrong word to describe the scope of what was scientifically predictable,” and “a mistake,” even though they had numerous opportunities to do so during the ‘012 patent reexamination.

55. In 2007, for example, while the ‘012 patent reexamination was ongoing, one of Pfizer’s competitors highlighted the discrepancy between Pfizer’s Canadian claims and its United States claims directed to non-human animals in a Canadian lawsuit involving the ‘446 patent. Specifically, in Canadian Case No. T-1314-05, Pfizer Canada Inc. and Pfizer Ireland sued Apotex Inc. and the Canadian Minister of Health in Canadian Federal Court to prevent Apotex from receiving regulatory approval to market a generic version of VIAGRA® in Canada until after the expiration of the ‘446 patent. Apotex argued in the case that Pfizer R&D’s Canadian Disclaimer was unlawful, and that the disclaimed claims consequently were invalid. Apotex explicitly called attention to the fact that although Pfizer disclaimed the non-human animal subject matter in the ‘446 patent, Pfizer failed to disclaim the corresponding subject matter in the ‘012 patent in the United States. In its May 11, 2007 Memorandum of Fact and Law, Apotex stated:

> 108. Although Pfizer alleges that the first disclaimer (December 2002) corrects various mistakes, it is curious that the corresponding U.S. patent, U.S. 6,469,012, which issued October 22, 2002, claims the treatment of ED in a male animal, the same "mistake" corrected in the '446 Patent, which issued four years earlier.

56. In Apotex's subsequent appeal ("Canadian Case No. A-484-07") from the Canadian Federal Court's decision in Canadian Case No. T-1314-05 (collectively, "Canadian Apotex litigation"), Apotex again pointed out – while the '012 patent reexamination was ongoing – the discrepancy between Pfizer's Canadian claims and its United States claims directed to non-human animals. In its April 8, 2008 Memorandum of Fact and Law, Apotex stated:

> 104. Although Pfizer alleges that the first disclaimer (December 2002) corrects various mistakes, the corresponding U.S. Patent, U.S. 6,469,012, which issued October 22, 2002, claims the treatment of ED in a male animal, the same "mistake" corrected in the '446 patent, which issued four years earlier.

57. Upon information and belief, however, the Patentees did not disclose to the PTO during the '012 patent reexamination either Apotex's May 11, 2007 Memorandum of Fact and Law or Apotex's April 8, 2008 Memorandum of Fact and Law (collectively, "Apotex Memoranda"), nor did the Patentees otherwise expressly inform the PTO of the discrepancy between Pfizer's Canadian claims and its United States claims directed to non-human animals.

58. Upon information and belief, the Patentees deliberately buried the Ellis Affidavit among the thousands of references the Patentees submitted to the PTO during the '012 patent reexamination. During the course of the six and a half year '012 patent reexamination, the Patentees filed approximately 30 information disclosure statements, identifying more than 2,000 references. In 2010 alone, the Patentees submitted at least nine information disclosure statements that included more than 600 references containing more than 18,000 pages. Just a

few months ago on March 30, 2010, (a) after the Patentees already had submitted thousands of references to the PTO, (b) after the Patentees already had submitted papers to the PTO to cancel claim 24 of the '012 patent to resolve the only issue remaining in the '012 patent reexamination, and effectively end the reexamination proceeding on the merits, (c) after Pfizer already had filed the Complaint in this action, (d) nearly four and a half years after Pfizer Ireland filed the Ellis Affidavit in Canada, and (e) nearly seven and a half years after Pfizer R&D filed the Canadian Disclaimer, the Patentees finally submitted to the PTO an information disclosure statement that simply listed the Ellis Affidavit among 48 other references. The Patentees' March 30, 2010 Information Disclosure Statement did not specifically draw the PTO's attention to the Ellis Affidavit, or to ¶¶ 59 and 60 thereof regarding the Canadian Disclaimer, from among the dozens of other references the Patentees submitted to the PTO that day, the hundreds of others submitted in 2010, or the thousands of references previously disclosed during the '012 patent reexamination. Upon information and belief, the Patentees studiously avoided telling the PTO that they knew that the claims in the '012 patent directed to the treatment of non-human animals were overbroad and invalid, and that the term "animal" is "much too broad in scope," "the wrong word to describe the scope of what was scientifically predictable," and "a mistake."

59. The acts of concealment by Dr. Ellis and the Patentees described in Paragraphs 48–58 above prevented the PTO from learning that the animal claims were overbroad and invalid during the '012 patent reexamination. That information was highly material to the patentability of those animal claims. Through their acts of concealment, Dr. Ellis and the Patentees prevented the PTO from making it a matter of public record that the animal claims in the '012 patent are overbroad and invalid, and enabled the Patentees to improperly take advantage of the monopoly secured by those invalid claims.

60. Dr. Ellis's and the Patentees' highly material omissions and misleading conduct during the '012 patent reexamination renders the '012 patent unenforceable. As described above in Paragraphs 48–59, those highly material omissions and that misleading conduct during the '012 patent reexamination include (i) Dr. Ellis's failure and the Patentees' failure to affirmatively inform the PTO that the claims directed to treatment of non-human animals are overbroad and invalid, or that the term "animal" was "much too broad in scope," "the wrong word to describe the scope of what was scientifically predictable," and "a mistake," (ii) the Patentees' failure to cancel the claims of the '012 patent directed to treating erectile dysfunction in non-human animals or to otherwise disclaim the subject matter in those claims directed to non-human animals, (iii) the Patentees' four and a half year delay in disclosing the existence of the Ellis Affidavit and the Patentees' ultimate burying of the Ellis Affidavit among many thousands of other references that the Patentees submitted to the PTO during the '012 patent reexamination, and (iv) the Patentees' failure to disclose to the PTO the highly material Apotex Memoranda at any time during the '012 patent reexamination. Upon information and belief, Dr. Ellis and the Patentees, including at least Messrs. Benson and Jones, acted with deceptive intent to ensure that Pfizer would not have to surrender any part of its broad monopoly on using sildenafil citrate to treat erectile dysfunction in any animal, and to ensure that the inequitable conduct they committed during the '012 patent prosecution (as described in Paragraphs 15–47 above) would remain hidden and undiscovered.

61. Teva USA is entitled to a declaratory judgment that all of the claims of the '012 patent are unenforceable because Dr. Ellis, Pfizer Inc. and Pfizer Inc.'s patent counsel, including at least Messrs. Benson, Jones and O'Rourke, engaged in inequitable conduct during the prosecution and reexamination of the '012 patent detailed in Paragraphs 15–60 above.

PRAYER FOR RELIEF

WHEREFORE, Teva USA requests that the Court enter Judgment in its favor and against Plaintiffs and Counterclaim-Defendants Pfizer Inc., Pfizer Limited and Pfizer Ireland Pharmaceuticals as follows:

A. Dismissing all claims against Teva USA in Pfizer's Complaint with prejudice;

B. Declaring that Teva USA has not infringed, contributed to the infringement of, or induced the infringement of, and will not infringe, contribute to the infringement of, or induce the infringement of claim 25 or claim 26 of the '012 patent by engaging in the commercial manufacture, use, sale, offer for sale and/or importation of Teva's ANDA Products identified in Teva's ANDA No. 77-342;

C. Declaring invalid claim 25 and claim 26 of the '012 patent;

D. Declaring the '012 patent and each of its claims unenforceable due to inequitable conduct;

E. Adjudging that Plaintiffs and Counterclaim-Defendants are not entitled to any declaratory or injunctive relief or any alleged damages for alleged patent infringement by Teva USA;

F. Adjudging this to be an exceptional case under 35 U.S.C. § 285, and awarding to Teva USA its reasonable attorney fees, costs and expenses; and

G. Granting to Teva USA such other and further relief as this Court may deem just, proper or equitable.

Dated: January 26, 2011

Respectfully submitted,

/s/

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CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of January, 2011, I will electronically file the foregoing Teva's Revised First Amended Answer and Counterclaim with the Clerk of Court using the CM/ECF system, which will then send a notification of such filing to the following counsel of record:

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